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ABSTRACT

This report of the Subcommittee on Oversight and Investigation focuses on issues raised by the marketing of commercially prepared infant formulas that were nutritionally deficient. In this context, the report examines the scope of FDA authority to protect the public and the manner in which the FDA carries out its responsibilities with respect to product recalls. Additionally, the report reviews existing standards and regulations for infant formulas, and reports findings of an investigation into the manner in which one manufacturer, Syntex Laboratories Inc. of Palo Alto, California, complied with these regulations. This investigation revealed that over 100 infants became ill, some severely so, as a result of having been dependent on the formula for a long period of time. In evaluating the actions of the FDA and this manufacturer, the subcommittee found that little had been done to minimize or prevent this affair. Consequently, it was recommended: (1) that congress enact legislation to create a separate category of food known as infant formula: (2) that infant formula contain all nutrients recognized as essential: (3) that the formula be tested at critical times for nutritional adequacy: and (4) that the FDA be given the ability to inspect records of infant formula manufacturers. (Author/MP)

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INFANT FORMULA: OUR CHILDREN NEED BETTER PROTECTION

REPORT

together with

DISSENTING VIEWS

BY THE

SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

OF THE

COMMITTEE ON INTERSTATE AND FOREIGN COMMERCE

HOUSE OF REPRESENTATIVES

NINETY-SIXTH CONGRESS

SECOND SESSION

FEBRUARY 1980

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WASHINGTON, D.C. 20515

February 29, 1980

Honorable Harley O. Staggers
Chairman
Interstate and Foreign Commerce
Committee
Washington, D.C. 20515

Dear Mr. Chairman:

The attached report of the Subcommittee on Oversight and Investigations focuses on issues raised by the marketing of commercially prepared infant formulas that were nutritionally deficient. In this context, the report examines the scope of FDA authority to protect the public, and the manner in which the FDA carries out its responsibilities with respect to product recalls. Moreover, the report reviews existing standards and regulations for infant formulas as well as the manner in which the manufacfacturer performed in this instance.

Our investigation found that over one hundred infants became ill--some severely so--as a result of having been dependent on the formula for a period of time. Fortunately, there were no known deaths. However, the long term effects of extended use are unknown. In evaluating the actions of FDA and the manufacturer, Syntex, the Subcommittee found that they had passed over a number of opportunities to take action that would have minimized or even prevented this tragic affair. For example, the FDA maintained outmoded standards for the composition of infant formula. Moreover, its internal procedures were defective in that the health experts were unilaterally overruled by compliance officials. And, the FDA was lackadaisical in its approach to the recall of the deficient product allowing it to remain on the market three months after it was determined to be life-threatening. As for Syntex, it failed to perform tests for nutritional adequacy during a critical interval, an action that resulted in the preparation and release for sale of chloride-deficient, mislabeled infant formulas.

The Subcommittee recommends that Congress enact legislation to create a separate category of food known as infant formula; that infant formula must contain all nutrients recognized as essential;

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that it be tested at critical times for nutritional adequacy; and, that the FDA be given the ability to inspect records of infant formula manufacturers. Hopefully, the report will assist our Committee's Subcommittee on Health and Environment in its consideration of legislative remedies to address this potentially serious situation.

Further, the Subcommittee recommends certain changes in FDA procedures. And finally, because of the apparent violations of the Food, Drug and Cosmetic Act, the Subcommittee is referring this matter to the Justice Department in order to seek a prosecutive opinion.

In closing, I would like to take this opportunity to acknowledge with appreciation the excellent contribution of Dr. Kenneth Gardner, who has been serving as a Congressional Science Fellow on the staff of the Subcommittee. Dr. Gardner, a faculty member at the Medical School of the University of New Mexico, has provided expertise and invaluable assistance during the course of this investigation.

Sincerely,

Bob Eckhardt
Chairman
Subcommittee on
Oversight and Investigations

Enclosure

(IV)

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INFANT FORMULA: OUR CHILDREN NEED BETTER PROTECTION

PROLOGUE

"Infant formulas are uniquely important to the health of this Nation. Many infants are given formulas as the sole source of nutrients for the first several months of their lives. Their proper development and health is determined to a large extent by the quality of nutrition they get during this critical time.

"I regard regulation of infant formulas as among the most important responsibilities of FDA. There is no margin for error in their composition and production." [Statement of Dr. Jere Goyan, FDA Commissioner, issued on the eve of the subcommittee's hearing.]

The statement of the newly appointed Commissioner reveals an understanding of the absolute necessity for healthful infant formulas. At the same time, however, it stands in stark contrast to the FDA's inept performance when the agency was called on to deal with a life-threatening situation involving infant formulas. Indeed, an equivalent degree of sensitivity was not immediately evident in the Commissioner's own testimony. The subcommittee is hopeful that the near-tragic circumstances of the episode at hand will heighten future FDA and manufacturer performance to levels matching the words of the Commissioner.

I. INTRODUCTION AND METHODOLOGY

Commercially prepared infant formulas provide a feeding alternative or supplement to babies who are intolerant of cows' milk and whose mothers do not breast feed. The composition of these formulas is established by their manufacturers. Products utilizing a soy-bean base are especially popular, as evidenced by the fact that in the United States there are an estimated 20,000 infants on soy-based formulas at any given time. The composition of these formulas is a matter of public interest.

In 1967, the Committee on Nutrition (CON) of the American Academy of Pediatrics (AAP) proposed standards for the composition of manufactured infant formula.[1] It did so in anticipation of a review by the Food and Drug Administration (FDA) of all foods designed for special dietary use, including infant formulas. In 1971, the FDA acted pursuant to its authorities under Chapter IV of the Food, Drug and Cosmetic Act and promulgated standards for the composition of infant formula. These standards were similar to those proposed by the Committee on Nutrition.[2]

[1] American Academy of Pediatrics Committee on Nutrition: Proposed changes in Food and Drug Administration regulations concerning formula products and vitamin-mineral dietary supplements for infants. *Pediatrics* 40: 916,1967.

[2] CFR § 105.3—105.65 (1971).

In 1974, experts of the AAP examined the need for new recommendations concerning the composition of infant formulas. Developments in the field of nutrition were indicating that nutrients might adversely interact with one another, that vegetable rather than milk protein was becoming increasingly popular as a formula base, and that there was a growing need for uniformity in standards of composition.

In 1976, the AAP's Committee published revised nutritional standards for infant formulas.[3] FDA regulations, however, were not updated then or at anytime since its 1971 action. Current FDA standards for the composition of manufactured infant formulas, therefore, do not reflect the latest professionally recommended minimum levels for essential nutrients, and this played a part in the near tragic events described in this report.

The Subcommittee on Oversight and Investigations entered an investigation of soy based formula products at the request of two subcommittee members, Congressman Ron Mottl, Democrat of Ohio, and Congressman Albert Gore, Democrat of Tennessee. Their request was based upon a Washington, D.C., television program, "The Investigators". The program charged that two baby formulas manufactured by Syntex Laboratories, Inc.—Neo-Mull-Soy and Cho-Free—were nutritionally inadequate, that clinical illness was accompanying their use, and that cans of the formula could still be found on store shelves well after a recall should have been completed.[4]

The subcommittee examined the specific recall of these products as well as more general issues and allegations surrounding infant formulas. The subcommittee sought answers to the following questions:

1. What was the relationship between the use of these products and resulting clinical illnesses, and how severe were the health effects?
2. Did FDA carry out its responsibilities for determining the need for and the monitoring of the recall in an expeditious and appropriate fashion?
3. Does the FDA have adequate authority to protect the public in incidents of this kind?
4. Did the manufacturer carry out its responsibilites in an expeditious and appropriate fashion?
5. Are existing standards and regulations for infant formulas, including premarket ingredient testing, adequate?
6. Are infant formulas a unique category of food that require treatment distinct from other foods under the Food, Drug and Cosmetic Act?

II. SUMMARY OF FINDINGS AND CONCLUSIONS

A. The Subcommittee on Oversight and Investigations finds that the Food and Drug Administration:

1. Performed with respect to the recall of Cho-Free and Neo-Mull-Soy in a manner which approached total disregard for the health and safety of the affected infants.

(a) The classification assigned to the recall by FDA compliance officials was improper. FDA scientific experts (Health Hazard Evaluation Board) unanimously concluded that the sustained use of chloride-deficient Cho-Free and Neo-Mull-Soy could cause serious health

[3] Pediatrics, vol. 57, No. 2, February 1976, pp. 278–285 (hereinafter cited as AAP Standards).
[4] Press Release: "Baby Formula: The Hidden Danger", WRC-TV, Oct. 25, 1979.

consequences or death. However, FDA compliance officials overruled this judgment and instead of designating a Class I recall, which life-threatening situations require, designated the recall Class II, signifying that illness from use of these products was reversible or remote.

(b) FDA monitoring of the recall was inordinately delayed. The recall commenced on August 2, 1979, but FDA oversight of recall effectiveness did not begin until October 24, 1979.

(c) The level which the FDA established to gauge the effectiveness of the recall was inadequate. FDA directed that a Level C effectiveness check be implemented to evaluate the recall's impact. It required that only 10 percent of consignees be contacted for evidence of compliance. In light of the life threatening determination made by the FDA Health Hazard Evaluation Board, the level of effectiveness check was not appropriate; it did not insure that all of the hazardous products were removed from the market.

2. Retained regulations for the nutritional composition of manufactured infant formulas that are outdated and allowed unsafe formulas to be marketed. If the FDA had adopted the nearly four-year old recommendations of the AAP's nutritional experts, and specified chloride minimums in its regulations, the events described in this report might not have occurred.

B. The Subcommittee finds that Syntex Laboratories, Inc. of Palo Alto, Calif.:

1. Marketed, as Neo-Mull-Soy and Cho-Free, synthetic, soy-based infant formulas that contained deficient concentrations of an essential nutrient, chloride. The formulas caused life-threatening disease when used as a sole source food. Because chloride is an essential nutrient that should be included in infant formula and because Syntext failed to include adequate amounts of chloride in Neo-Mull-Soy and Cho-Free, the formula was "unfit for food" and had a "valuable constituent omitted". Therefore, the subcommittee concludes that Syntex products were adulterated in apparent violation of section 402 of the Food, Drug and Cosmetic Act.

2. Placed labels on cans of Cho-Free that indicated chloride concentrations were 9 milliequivalents per liter of final formula. In fact, chloride concentrations were substantially lower. The subcommittee concludes that Cho-Free was mislabeled as to chloride content, in apparent violation of section 403(a) of the Food, Drug and Cosmetic Act.

3. Placed labels on cans of Neo-Mull-Soy which, while not listing chloride, listed salt (sodium chloride) in an amount sufficient to yield a chloride concentration of 5.1 milliequivalents per liter (quart) of final formula. Analysis of the product disclosed a chloride concentration of 2.5 milliequivalents per liter (quart). The subcommittee concludes that Neo-Mull-Soy was mislabeled, in apparent violation of section 403(a) of the Food, Drug and Cosmetic Act.

4. Placed in the Physicians Desk Reference (PDR) a statement that Cho-Free formula contains 9 milliequivalents of chloride per quart of properly diluted product. Chloride concentrations were far less. The statement finds that the PDR statement was inaccurate and misleading and was in apparent violation of section 403(a) of the Food, Drug and Cosmetic Act.

5. Placed in the Physicians Desk Reference (PDR) a statement that Cho-Free formula (with its listing of 9 milliequivalents of chloride

per quart) is the same as Neo-Mull-Soy except for carbohydrate content. This statement led physicians to the erroneous conclusion that Neo-Mull-Soy contained adequate chloride concentrations. The subcommittee finds that the PDR statement was misleading and in apparent violation of section 403(a) of the Food, Drug and Cosmetic Act.

6. Marketed Cho-Free and Neo-Mull-Soy which were apparently adulterated and misbranded as defined by sections 402 and 403 respectively, of the Food, Drug and Cosmetic Act. The subcommittee therefore concludes that Syntex is in apparent violation of section 301(a) of the Food, Drug, and Cosmetic Act. Section 301(a) prohibits introducing into interstate commerce any food, drug, device or cosmetic that is adulterated or misbranded.

7. Failed to cooperate with the Food and Drug Administration to the extent necessary to assure appropriate Agency monitoring of the recall of chloride deficient products from consignees' shelves.

C. The subcommittee further finds that, with respect to manufactured infant formulas, a need exists to:

1. Strengthen current requirements for composition.

2. Mandate testing for nutritional adequacy before marketing and after any change in the manufacturing process.

3. Establish more stringent procedures for recall.

III. SUMMARY OF RECOMMENDATIONS

The Subcommittee recommends:

(A) That Congress enact legislation to—

1. Create a separate category of food designated "infant formulas", to include only those products that are intended to provide a nutritionally adequate diet to normal infants.

2. Require that infant formulas contain all nutrients recognized as essential.

3. Require that a product contain these essential nutrients before permitting the label, "infant formula".

4. Require that all infant formulas be tested for their nutritional adequacy before marketing and after any change in the manufacturing process.

5. Require that recalls of infant formula products be conducted as class I recalls, the FDA classification which recognizes a potential for serious adverse health consequences or death.

6. Grant FDA authority, in infant recall situations, to inspect manufacturer's records and to enforce compliance with recall directives.

7. Require that 100 percent of consignees be contacted during monitoring of infant formula recalls, a procedure defined as a "Level A effectiveness check" by FDA.

(B) That the FDA—

1. Establish procedures that more precisely integrate decisions of its Health Hazard Evaluation Board into the classification of recalls. These procedures must preclude administrative downgrading of a determination by the Board, unless by express action of the Commissioner.

2. Review and clarify its procedures and regulations relating to the classification and the performance of effectiveness checks on recalls.

FDA administrative mechanisms must insure that manufacturers understand their responsibilities in a recall and that monitoring is performed expeditiously and adequately.

3. Establish procedures that require that consignees—
   a. be promptly notified of infant formula recalls,
   b. acknowledge they have been notified, and
   c. provide verification that they have complied.

(C) That the Department of Justice—

1. Review the record of the Neo-Mull-Soy and Cho-Free cases and provide a prosecutive opinion with respect to apparent violations of sections 301(b), 402 and 403(b) of the Food, Drug and Cosmetic Act, or any other Federal law.

IV. CASE STUDY—NEO-MULL-SOY AND CHO-FREE

On November 1, 1979, the Subcommittee held a public hearing concerning two infant formula products, Neo-Mull-Soy and Cho-Free. At the hearing, evidence was presented that these two products had seriously deficient chloride levels. According to testimony, use of the infant formula prior to August 1, 1979 was associated with at least 26 documented cases of hypochloremic metabolic alkalosis,[5] a chemical abnormality of the body caused by deficient chloride intake. One witness, Dr. Shane Roy, a pediatric nephrologist from Memphis, Tenn., who was one of the first physicians to deduce that nutritionally inadequate formula was at fault, described three cases from his practice.[6] He had diagnosed the first case on June 20th and the third in late July 1979. He considered the occurrence of three such cases within a period of one month in one geographic area to be highly unusual. Dr. Roy, realizing that all three patients had been on Neo-Mull-Soy as their sole source of nourishment, telephoned his findings to Syntex Laboratories, Inc. on July 24, 1979, and inquired if other cases were linked to use of Syntex formula.[7] Syntex responded that no other cases had been reported. On July 26th Syntex contacted Dr. Roy to tell him that four additional cases had come to its attention; two from Staten Island, New York, one from Kentucky, and one from Memphis, Tennessee.

On July 26, 1979, the Memphis-Shelby County Health Department in Memphis, Tennessee reported the hospital admissions of Dr. Roy's patients to the Center for Disease Control (CDC), an agency within the Department of Health, Education and Welfare (HEW).[8] Following receipt of this information, implicating Neo-Mull-Soy as the cause of dangerously low low blood levels of chloride and potassium, the CDC surveyed pediatric nephrologists throughout the country.[9] Thirty-one cases of alkalosis were uncovered by the CDC; 26 were associated with the use of Neo-Mull-Soy.[10]

The Food and Drug Administration and the manufacturer, Syntex, were thereafter notified of the findings of CDC.[11] On August 1, 1979

[5] "Infant Formula", hearings before the Subcommittee on Oversight and Investigations, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, 96th Congress, 1st session, Nov. 1, 1979, Serial No. 96-79 (hereinafter cited as *Hearings*) at p. 9.
[6] *Id.* at pp. 6–7.
[7] *Id* at p. 6.
[8] *Id.* at 9.
[9] *Id.*
[10] *Id.*
[11] *Id.*

Syntex convened a small meeting of pediatric nephrologists and subsequently announced a recall of its infant formulas.[12] The recall documents were approved by the FDA and went into effect on August 2, 1979.[13]

The events leading to the recall were established from testimony at the hearing and from written reports obtained from FDA:

(a) In late 1977 Syntex, on its own violation, discontinued analyses for chloride on its soy-based infant formulas, Cho-Free and Neo-Mull-Soy.[14] [15]

(b) Beginning in March-April 1978, the company reformulated these products and voluntarily discontinued adding salt (sodium chloride) in an effort to reduce sodium content.[16] [17]

(c) When the Syntex formulas were cited in the pathogenesis of clinical illness by Dr. Roy and others in July 1979, the company retrospectively analyzed samples from 1978–79 of formula.[18] They found that most lots were deficient in chloride.[19] Random analyses by FDA and private laboratories confirmed the finding.[20] [21] For example, of more than 90 lots processed during the first 192 days of 1979,and analyzed by Syntex, the majority contained one-third or less of the AAP-recommended minimum chloride concentration.[22] Only four of 99 lots contained chloride in amounts that approximated the AAP recommended minimum of 11 milliequivalents of chloride per liter of formula.[23]

(d) As of August 31, 1979, about 100 cases were diagnosed in a registry compiled by CDC.[24]

V. THE RECALL

A. FDA authority and procedures

The Food and Drug Administration has defined policies and procedures for product recalls. Recalls are undertaken voluntarily by manufacturers and distributors, or at the request of FDA, when the agency considers a product to be in violation of the laws it administers. The FDA does not have the authority to mandate product recalls. When the FDA requests a recall under its administrative regulations, it has no authority to impose sanctions against a firm that refuses to carry out the recall. While it can obtain a court order directing it to seize any product that it regulates, the FDA has viewed this process as cumbersome and has rarely invoked it.

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[13] *Id.*
[12] *Id.* at pp. 27 28.
[14] *Id.* at pp. 88–90.
[15] "Establishment Inspection Report" by FDA Inspectors S. P. Brudeerle and B. H. McCullough, Elgin, Ill., Aug. 1, 2, 9, 1979, at p. 17 (hereinafter cited as EIR-Elgin).
[16] *Id.* at pp. 2 and 8.
[17] "Establishment Inspection Report" by FDA Inspectors W. L. Vaundell and A. P. Scott, Palo Alto, Calif., Aug. 28, Sept. 5, and Sept. 17, 1979, at p. 7.
[18] Memorandum of Syntex Laboratories, Inc. from John Kjellstrand, Elgin, Illinois to Jack Conen, re: Analysis Results—1979 Products (undated); submitted to subcommittee on Oct. 30, 1979 (hereinafter cited as *Syntex Memo*).
[19] *Id.*
[20] Letter from Shane Roy, M.D. to Subcommittee on Oversight and Investigations, Jan. 24, 1980.
[21] FDA Chicago District Office, Sample No. 79-161-991 of Cho-Free Formula Base, Aug. 16, 1979.
[22] *Syntex Memo*, *supra* note 18.
[23] *Id.*
[24] *Hearings*, *supra* note 5 at p. 9.

This study is limited to an examination of FDA recall procedures as it relates to infant formulas. However, it does raise anew the need for broad recall powers for the FDA.[25]

B. Recall actions

The FDA, by approving the documents of Syntex on August 2, 1979, established that the chloride deficient products would be removed through the voluntary recall process. The FDA could have sought a court ordered seizure, but did not choose that pathway. While it is not clear whether seizure was seriously considered by the FDA, the subcommittee believes that in life-threatening situations, court ordered seizures should always be considered as an option.

Once a decision is made to follow the voluntary process, FDA regulations call for a recall strategy to be established.[26] Recall strategy requires that four critical actions be taken: (1) evaluation of health hazard by an ad hoc committee, (2) designation of the class of recall (i.e., class I, class II, etc.), (3) designation of the level of depth to which recall is to be pursued, and (4) creation of a program to verify, through checks, the effectiveness of the recall.

In the *Cho-Free—Neo-Mull-Soy* case, the level of recall depth extended to the consumer, a level considered appropriate by the Subcommittee because of the life-threatening danger of the products. In contrast, the Subcommittee saw reason to question decisions made by FDA compliance officials in relation to the remaining three categories of recall strategy.

1. *Action by the Health Hazard Evaluation Board in the Cho-Free and Neo-Mull-Soy Recall.*—FDA regulatory procedures call for the Director of the Bureau of Foods to select a group of scientists who will evaluate the level of health hazard of a product being considered for recall. Based upon this evaluation, FDA administrative officials assign a classification to the recall.[27]

Dr. John E. Vanderveen, Director, Division of Nutrition, Bureau of Foods, FDA, who was a member of the Board in this instance, testified before the Subcommittee that he initiated the convening of the Health Hazard Evaluation Board of the FDA on August 2, 1979.[28] Dr. Vanderveen reported that at this meeting the Board voted unanimously to declare the soy protein infant formulas manufactured by Syntex Laboratories, Inc. a potentially life-threatening sub-acute hazard.[29] The following document presents the minutes of that August 2d meeting.

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[25] The Subcommittee on Oversight and Investigations, in its Report on Regulatory Reform ("Federal Regulation and Regulatory Reform", 94th Congress, October 1976, pp. 296–300) examined the issue of recalls relative to cardiac pacemakers. In that report the Subcommittee stated that it "... believes that the agency' recall procedures without the appropriate statutory support is an ineffective way to deal with life and death issues." Furthermore, the Subcommittee noted that in 1971, the House Committee on Government Operations discussed this point and issued a report calling for FDA to review the need for additional legislation on recall. ("Recall Procedures of the Food and Drug Administration," Committee on Government Operations, U.S. House of Representatives, House Report 92–585, October 1971) Subsequent to these reports, the FDA has not aggressively sought recall authority. In fact, on June 16, 1978, the Commissioner of FDA issued revised regulations concerning enforcement procedures in which the Commissioner acknowledged but did not seek to change the fact that the Federal Food, Drug and Cosmetic Act and the Public Health Service Act have no specific provisions to authorize the agency to order administratively the recall of violative foods, drugs and cosmetics and biologics.

[26] 21 CFR part 7.

[27] *Id.*

[28] *Hearings, supra* note 5, at p. 33.

[29] *Id.* at p. 34.

EVALUATION FORM, HEALTH HAZARD EVALUATION BOARD, BUREAU OF FOODS, FDA

New Mull Sy / Soy Formula Cases Reported to CDC Ready To 93 6

The Problem: Chlorine Formula Cases Nature of this specific problem:
low chloride levels

B No.: 166
Compliance No.:

☐ Hypothetical clinical situation
☒ known clinical disease or injury

Nature of Hazard			Possible Organ Systems Affected	
General Nature	Clinical Nature of Disorder 5/			
Life threatening 1/	Acute (EMERGENCY)		Blood & lymphatic	
Life threatening 1/	Subacute	X	Cardio- & peripheral vascular	
	Chronic		Dental & oral	
Severe 2/	Acute		Ear, nose & throat	
	Subacute		Endocrine	
	Chronic		Eye	X
Moderate 3/	Acute		Gastrointestinal	X
	Subacute		Genitourinary	X
Moderate 3/	Chronic		Gynecologic & obstetric	
Limited or mild 4/	Acute		Liver & bilary	
	Subacute		Musculoskeletal	
	Chronic		Nervous	
None anticipated	None		Neuropsychiatric	
			Respiratory	
			in & connective tissue	

As of today (8-2-79) some 31 infants scattered throughout the U.S. have been reported as cases of metabolic alkalosis. These infants have been on soy protein infant formulas manufactured and distributed by Syntex Corp. No deaths have been reported and when removed from the soy based infant formula and treated for alkalosis these infants have apparently recovered. Although the potential for hazard from use of these products has not resulted in any known deaths in the 31 cases reported to date, the Health Hazard Evaluation Board voted unanimously to declare this a potential life-threatening sub-acute hazard. The Board felt that although adequate treatment could prevent death, the possibility of infants on this formula and in distress who did not receive adequate care could result in a life threatening situation.

Comments & summary

1/ significant probability of death
2/ reasonable probability of significant disability; deaths rare
3/ reasonable possibility of transient but significant disability; reasonable possibility of permanent minor disability
4/ reasonable possibility of transient minor disability; annoying physical complaint
5/ Acute: maximum general effect attained in minutes/hours/one day
Subacute: maximum general effect attained in days/one week
Chronic: maximum general effect attained in weeks/months/years

Dr. F. Cordle
Dr. J.E. Vanden for Dr. Forbes
Dr. J.G. Chopra
Dr. W.V. Eisenberg for Dr. Read

Chairman or Authorized Representative

As indica ed by the minutes, the Health Hazard Evaluation Board various decision options. The Board designated the hazard from use of these products as "life threatening" and the probability of death from their use as significant. Furthermore, it declared the clinical nature of the hazard to be "subacute", that is, "maximum general effect attained in days/one week."

2. *Classification of the Cho-Free and Neo-Mull-Soy Recall.*—Operating under FDA regulatory guidelines, the Health Hazard Evaluation Board reported its findings to the FDA Division of Regulatory Guidance which has responsibility for undertaking the recall. At this point, the Division of Regulatory Guidance classified the recall of the formulas as Class II, which had the effect of directly overriding the recommendation of the Health Hazard Board and disregarding FDA regulations which distinguish between Class I and Class II recalls:

> Class I is a situation in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death.
>
> Class II is a situation in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote.[30]

Congressman Norman Lent, Republican of New York, expressed subcommittee sentiment concerning the downgrading of the Board's determination:

> Congressman LENT. I am reading these minutes . . . It states, "life threatening," footnote 1, "significant probability of death." That is a Class I hazard, is it not? [31]
>
> I have to say that I have a lot of difficulty understanding how the mind of man works. The so-called minutes speak for themselves, of course. It would seem to me that somewhere between the meeting and what actually happened somebody changed this thing from a Class I recall into a Class 2 recall. The ramifications of that change are, according to the regulations, quite significant.[32]

Mr. Curtis C. Coker, Jr., Assistant to the Director, Division of Regulatory Guidance, Bureau of Foods, testified that he was responsible for the recommendation which led to the Class II recall. In support of his action. Mr. Coker argued that the Health Hazard Evaluation Board felt the risk of death was extremely remote and that irreversible health consequences would not occur.[33]

Mr. Coker's view of the Board's findings were not substantiated either by the minutes of the Board's meeting or during the subcommittee's hearing. Dr. Vanderveen reiterated the decision of the Board in testimony at the hearing: "We intended to indicate it was a life-threatening situation." [34] He testified further that the Board reached no conclusion with respect to the irreversibility of health consequences.[35] The inconclusive view on long term consequences of chloride

[30] 21 CFR 7.42
[31] *Hearings, supra* note 5, at p. 42.
[32] *Id.* at p. 43.
[33] *Id.* at p. 36.
[34] *Id.* at p. 38.
[35] *Id.*

deprivation was buttressed by Dr. Roy who testified that science has not yet made that determination.[36]

Testimony was sought from Commissioner Goyan concerning the recall classification. He initially stated that he endorsed the Class II determination:

> I have had an opportunity to review the decision now. It is my belief that the decision at the time was correct to label it Class 2.[37]

He was questioned regarding the legal justification for his endorsement, particularly in light of the Board's classification:

> Dr. GOYAN. It is my understanding that the difference between Class I and Class 2 was understood to be somewhat different from the regulations you are pointing out . . .
>
> Mr. GORE. Where is that in the regulations Doctor? What section is that?
>
> Dr. GOYAN. I do not know that it is in the regulations.[38]

Congressman Mottl pursued the issue of classification from the standpoint of providing maximum protection to the public. He asked the Commissioner:

> Mr. MOTTL. . . . Wouldn't it have been more prudent, if there is a close call, to be on the side of prevention that nothing serious could happen in our society and categorizing it as No. 1 category rather than No. 2? Wouldn't that have been prudent, especially when your advisory committee said there was a significant likelihood of death?
>
> Dr. GOYAN. I think I am convinced you are correct in that. I think that if we are close on a decision we perhaps should, if we are to refer to it as error, we should err in that direction.[39]

Later in the hearing, Commissioner Goyan altered his initial viewpoint of the classification. When Congressman Lent ultimately sought an explanation for how a "life threatening situation" resulted in a Class II recall, Commissioner Goyan testified.

> I would like to say, however, that after my interaction later, I believe we would make it a class I today.[40]

The subcommittee believes that the recall should have been categorized as class I from its inception on August 2, 1979. On November 21, 1979, 3 weeks after the subcommittee's hearing, the FDA reclassified the recall as class I.[41]

The subcommittee concludes that FDA Regulatory Guidance officials overruled the recommendation of the FDA Health Hazard Evaluation Board without justification and misclassified the recall. The subcommittee believes that a unilateral power to overrule health experts should not rest with compliance officials. Therefore the Subcommittee recommends that FDA regulations be changed to explicitly

[36] *Id.* at p. 8.
[37] *Id.* at p. 39.
[38] *Id.*
[39] *Id.* at p. 40.
[40] *Id.* at p. 43.
[41] FDA Enforcement Report, Food and Drug Administration, Rockville, Md., Nov. 21, 1979, at p. 13.

preclude administrative downgrading of a determination by the Health Hazard Evaluation Board except by express action of the Commissioner.

3. *Designated Level of the Effectiveness Check in the Cho-Free and Neo-Mull-Soy Recall.*—The purpose of effectiveness checks is to verify that all consignees have received notification about the recall and have taken appropriate action. According to FDA regulation, a recalling firm will ordinarily be responsible for conducting effectiveness checks but the FDA will assist in this task when necessary and appropriate.[42] It is the responsibility of the Division of Regulatory Gudiance to recommend a level of effectiveness checks within the following regulatory categories.

> Level A—100 percent of the total number of consignees to be contacted;
>
> Level B—Some percentage of the total number of consignees to be contacted, which percentage is to be determined on a case-by-case basis, but is greater than 10 percent and less than 100 percent of the total number of consignees;
>
> Level C—10 percent of the total number of consignees to be contacted;
>
> Level D—2 percent of the total number of consignees to be contacted; or
>
> Level E—No effectiveness checks.[43]

In this case, the level of effectiveness check for the recall was set at level C. This meant that a check of 10 percent of Syntex consignees was required to obtain evidence of compliance. It emerged at the hearing that FDA was confused over the meaning of its own regulations. In response to a question by Congressman Lent, Commissioner Goyan explained the meaning of a Level C effectiveness check as follows:

> "For our Agency only. That is, we would check at that level [Level C]. Syntex was obligated to 100 percent. We were obligated to do a 10 percent check to indicate that they had been successful." [44]

Mr. Paul Freiman, President of Syntex Laboratories, Inc. described his understanding of Level C effectiveness checks as quite different than the FDA Commissioner.

> In light of these facts, the FDA classified the recall as one which requires effectiveness checks to be made with 10 percent of the customers to whom the sales are made. Syntex, although only required by enforcement policy to spot check 10 percent of its customers, actually contacted almost all of its customers in order to assure that products were removed from the store shelves.[45]

From the foregoing, it is evident that the FDA must review and clarify its procedures and regulations for both determining the level of effectiveness checks and communicating that determination to the manufacturer. If FDA wanted Syntex to spot check more than 10 percent of consignees it should have established a higher level of

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[42] 21 CFR part 7.42(b)(3).
[43] Id.
[44] Hearings, *supra* note 5, at p. 44.
[45] *Id.* at p. 65.

effectiveness check. The confusion that present procedures permit, both within the FDA and between the FDA and the manufacturer, must be eliminated.

There is yet one other aspect of the effectiveness check that needs to be addressed. Level C, with its check of only 10 percent of consignees, is not adequate to safeguard health when a life-threatening situation is involved, such as existed with respect to infant formula. It is imperative that procedures involving infant formula recall permit only Level A effectiveness checks to be made, when formula use poses such potentially serious consequences.

C. Monitoring of recall effectiveness

The subcommittee reviewed the manner in which the FDA monitored the recall effectiveness. Commissioner Goyan admitted during the hearing that the FDA did not make any effectiveness checks until a week before the hearing—almost 3 months after the agency's experts had determined that a life threatening situation existed. Dr. Goyan attributed this delay to communication problems [46] and to confusion between the San Francisco Regional Office and FDA headquarters.[47] FDA Associate Commissioner for Regulatory Affairs, J. Paul Hile, testified somewhat apologetically that FDA actions concerning the effectiveness check on this recall did "not reflect our procedures".[48]

The FDA's delay in this instance is inexcusable and intolerable. The agency must immediately evaluate its procedures and build in administrative mechanisms to insure that recalls are closely and effectively monitored. It would not appear to be unreasonable to expect that effectiveness checks of infant formula recall be commenced within one week after recall is initiated.

D. Success of recall

Both the FDA and Syntex testified that the recall was successful. Commissioner Goyan described the recall as 95 percent effective. However, his estimate of success was made as of October 31, 1979, fully 3 months after the danger was identified—a delay so long after recall inception that it could not yield a meaningful evaluation of recall success.

Moreover, the Commissioner's assessment even at the end of October appears to have been overly optimistic. According to information presented to the subcommittee, considerable formula remained on sale at that time, The General Accounting Office found formula on shelves in Detroit, Washington, New York, San Francisco, and Los Angeles; the National Broadcasting Co. affiliates found the product in stores in several cities around the country; and, the FDA found the product in the Washington D.C. area and so notified Syntex on October 19, 1979.[48] [49] Finally, Congressman Gore's staff discovered Neo-Mull-Soy on the shelves in Tennessee and as the Congressman characterized it, "everyone who looked for the recall products found it."[50]

[46] *Id.* at p. 24.
[47] *Id.* at p. 44.
[48] *Id.* at p. 33.
[49] Telegraphic message from Joseph P. Hile, FDA, to Mr. Paul Freiman, president, Syntex Laboratories, Inc., Oct. 19, 1979.
[50] *Hearings*, *supra* note 5, at p. 33.

Moreover, because FDA regulations relate effectiveness checks to a percentage of the total number of consignees and do not require consignees to acknowledge contact, the assignment of any numerical value to the relative level of effectiveness is senseless. During the hearing, Congressman Mottl suggested to Syntex President Freiman that the recall procedure would be strengthened by requiring wholesalers, manufacturers, and dealers to acknowledge receipt of recall notification. Mr. Freiman agreed that this could be a helpful step.[51]

The subcommittee therefore recommends that the FDA revise existing regulations to require consignees, after they have been notified of the recall, to acknowledge notification and provide verification that they have complied with the requested recall.

E. Failure by Syntex to cooperate with the FDA

The subcommittee established that Syntex failed to cooperate with FDA in two important areas. In the first instance, Syntex inexcusably excluded FDA from a meeting held in San Francisco on August 1, 1979. At that meeting, medical experts, including CDC personnel, discussed their findings with respect to children who were alkalotic after using Syntex formulas. At the subcommittee hearing, Dr. Vanderveen testified that FDA had requested permission to attend but that "Syntex refused to grant an invitation." [52]

Second, Syntex did not comply with FDA requests for information concerning the infant formula products. Syntex laboratories were visited by FDA regional staff on August 28, September 5, and September 17, 1979. Information sought but unavailable at those times still had not been provided by Syntex to FDA at the time of the November 1 hearing. Mr. Thompson of Syntex testified that all outstanding information would be supplied to FDA on the following day. However, on November 20, 1979, the subcommittee chairman was informed that 5 of 14 questions posed to Syntex by the FDA remained unanswered. These questions not only referred to past events but sought information concerning formula lots manufactured since the recall, and what tests, if any, had been performed on them.

While the level of Syntex cooperation left much to be desired, it is clear that part of the blame must be attributed to deficiencies in FDA procedures. Moreover, confusion existed within FDA itself as to the level of Syntex cooperation. On the one hand, the FDA's regional office met resistance to its requests for information and was excluded from a crucial meeting. On the other hand, Mr. Hile of the FDA's central office inexplicably described Syntex actions as fully cooperative.[53]

The possibility of company resistance raises anew the need for increased FDA authority to deal with urgent recall situations such as existed in this instance. FDA has no authority to force companies to respond to its requests for information. On that point, Dr. Shane Roy testified, "I have been somewhat naive, I think, in expecting that the FDA had the power to require or to ask of a formula manufacturer information related to their manufacture and quality control of that product . . ." [54] Moreover, FDA cannot force companies to

[51] *Id.* at pp. 97–98.
[52] *Id.* at p. 60.
[53] *Id.* at p. 45.
[54] *Id.* at p. 17.

expeditiously recall faulty products from the market. In the absence of court-ordered seizure action, the FDA must depend on manufacturer willingness to comply. Under such circumstances it is entirely possible that the FDA would choose to accept partial response to its directives, fearing that confrontation under present authorities could terminate cooperation entirely. In cases of infant formula recall, the Subcommittee believes that FDA must have the authority (a) to inspect manufacturers' records and (b) to enforce compliance with recall directives whenever a class I recall of infant formula is in effect.

VI. POSSIBLE VIOLATION OF LAW

According to an FDA memo of August 6, 1979, Syntex was in possible violation of two different sections of the Food, Drug and Cosmetic Act:[55] section 402 which defines the adulteration of an article of food and section 403 which defines the misbranding of an article of food.

A. *Adulteration (sec. 402)*

Section 402 of the act provides that "A food shall be deemed to be adulterated . . . if it is otherwise unfit for food"[56] . . . or "If any valuable constituent has been in whole or in part omitted or abstracted therefrom".[57]

Whether the Syntex formulas were adulterated and in violation of section 402 depends upon whether chloride is a valuable constituent or whether infant formula with insufficient amounts of chloride is unfit for food. The subcommittee believes that the facts demonstrated that the fitness of the formula is dependent, in part, upon chloride content, which clearly is a vital ingredient.

The deleterious potential of low chloride formula on infants was evidenced in this episode by (a) the decision of the FDA Health Hazard Evaluation Board that the chloride-deficient formulas represented a life-threatening hazard and (b) the testimony of physicians and parents at the hearing that clinical illness among infants was severe.[58] The importance of chloride to the overall nutritional adequacy of Cho-Free and Neo-Mull-Soy was manifest not only by the fact that the AAP's Committee on Nutrition recommended in 1976 a minimum concentration for chloride in infant formula but also by the fact that once the chloride deficiency was discovered, Syntex restored adequate amounts of chloride to its products. At least retrospectively Syntex considered chloride a constituent of value to their formulas.

Clouding the issue of chloride's value is the fact that FDA regulations in effect at the time of this incident did not list chloride as one of the important ingredients in infant formula. However, these regulations are based on pre-1971 scientific knowledge and opinion, since infant formula regulations were last promulgated by the FDA during that year. It is quite possible that if the FDA had updated its regulations by following those adopted in 1976 by the AAP, the events described in this report would have been avoided. Unfortunately, the FDA did not take that action until after tragedy struck.

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[55] 21 U.S.C. 342, 343.
[56] 21 U.S.C. 342(a)(3).
[57] 21 U.S.C. 342(b)(1).
[58] *Hearings, supra* note 5, at pp. 4–23.

On January 29, 1980 the FDA acknowledged the importance of chloride in infant formulas in a letter to the Subcommittee Chairman, as follows:

> We have undertaken a thorough review of our existing administrative and statutory authorities to determine if changes are needed. As a result of that assessment, we have decided to:
>
> Revise our existing regulation on the nutrient composition of infant foods (21 CFR 105.65) to incorporate additional essential nutrients such as chloride and to ensure that the regulation is in full accord with the nutrient quality guidelines of the American Academy of Pediatrics (AAP) and current knowledge of the most appropriate composition of infant formulas.[59]

With this acknowledgement by FDA, it would now appear that all parties agree that chloride is an essential ingredient of infant formula.

B. Misbranding (sec. 403)

Misbranding, in violation of the Food, Drug and Cosmetic Act, can occur by either labeling or advertising. In considering whether an article of food is misbranded two sections of the act must be considered:

> Section 201(n):[60]
>
> If an article is alleged to be misbranded because the labeling or advertising is misleading, then in determining whether the labeling or advertising is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertising relates under the conditions of use prescribed in the labeling or advertising thereof or under such conditions of use as are customary or usual.
>
> Section 403(a):[61]
>
> A food shall be deemed to be misbranded if (1) its labeling is false or misleading in any particular, or (2) in the case of a food to which section 411 applies, its advertising is false or misleading in a material respect or its labeling is in violation of section 411(b)(2)'.[62]

The subcommittee reviewed labeling and other product information provided to consumers and health professionals.

1. *Labeling.*—During 1978–79, Syntex marketed Cho-Free and Neo-Mull-Soy with labels that respectively specified a chloride content and a salt content in the list of ingredients. Because both products contained low to barely detectable concentrations of chloride, the Subcommittee explored the possibilities that both products were

[59] Letter from FDA Commissioner Jere Goyan to Congressman Eckhardt, Chairman, Subcommittee on Oversight and Investigations, Jan. 29, 1980.
[60] 21 U.S.C. 321(n).
[61] 21 U.S.C. 343(a).
[62] According to section 411(c)(3) and FDA regulations governing infant formula (21 C.F.C. 105.3), infant formula is a "food to which section 411 applies."

misrepresented as to their chloride contents. If Syntex had accurately represented the low-chloride content, ill effects suffered by over one hundred children may have been prevented.

a. Cho-Free labeling

Labels on cans of Cho-Free indicated that the product contained 0.32 grams of chloride per quart of formula after it was properly diluted 1:1 with water. Chloride in this concentration approximates 9 milliequivalents per liter. The 1976 AAP recommendation specified a minimum of 11 milliequivalents per liter.[63] Evidence presented at the hearing and documents obtained from the FDA demonstrated that Cho-Free chloride concentrations were substantially lower than either figure:

(i) An FDA Telex transmission of early August 1979 stated that "[A]nalytical work performed by recalling firm on all lots . . . manufactured since January 1, 1978, revealed the following range of chloride levels: 0.005 to 0.095 grams per quart" (0.14 to 2.6 milli equivalents per liter) of chloride.[64] The chloride level claimed by the label was reiterated in the Telex as 0.32 grams per quart.

(ii) Syntex analyses of Cho-Free formula Lots Nos. 0879, F1029, and 1459 disclosed chloride concentrations equivalent to 0.6, 6.0, and 6.6 milliequivalents per liter of diluted formula—5 percent, 55 percent and 60 percent, respectively, of the AAP recommended minimum and 7 percent, 67 percent and 73 percent, respectively, of the level claimed on the label.[65]

(iii) An FDA Collection Report on Sample Number 79–161–991 cited a case of metabolic alkalosis in an infant who had been fed from Cho-Free Lot No. E36[illegible]8, manufactured late in 1978.[66] An FDA analysis of aliquots from this lot demonstrated a chloride content equivalent to 0.111 grams per quart (3 milliequivalents per liter) of diluted formula.[67]

(iv) At the hearing, Mr. Thompson of Syntex was queried about the concentration of chloride in Cho-Free. He replied, "[T]here is no question but what there are lower chloride levels in there than are represented on the can . . ."[68]

From these facts the Subcommittee concludes that Syntex marketed Cho-Free in cans that were mislabeled as to the chloride content of the product in apparent violation of the Food, Drug and Cosmetic Act.

B. Neo-Mull-Soy labeling

Neo-Mull-Soy Label No. 07–2328–30 listed among ingredients "salt" at 0.03 grams per 100 grams. The significance of the word "salt" to Syntex Corporation emerged during testimony of Mr. Frieman: "Chloride is part of sodium chloride, which is salt".[69] In specific terms, chloride accounts for roughly 60 percent of the weight of salt and sodium roughly 40 percent. Thus a product containing 0.03 grams of "salt" per 100 grams contains 0.018 grams of chloride per 100 grams. This amount is equal to approximately 5 milliequivalents of chloride per liter of liquid product.

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[63] *AAP Standards*, supra note 3.
[64] FDA Telex from E. J. Cassidy, San Francisco District Office, to all FDA district offices, Aug. 6, 1979.
[65] *Syntex Memo*, *supra* note 18.
[66] *Supra* note 21.
[67] *Id.*
[68] *Hearings*, *supra* note 5, at p. 96.
[69] *Id.* at p. 80.

An FDA Establishment Report dated August 1, 2, 9, 1979, indicates that salt was not added to the Neo-Mull-Soy formula at the Syntex Elgin Plant as of March 27, 1978.[70] On products packaged three and one half months later, however, the Corporation used labels indicating that 0.03 grams of salt per 100 grams were present.[71]

On August 31, 1978, the FDA obtained cans of Neo-Mull-Soy Lot No. 1988C from the Elgin, Illinois plant of Syntex. These cans bore Neo-Mull-Soy Label No. 07–2328–30, listing a salt content in the product of 0.03 grams per 100 grams, an amount equal to 5 milliequivalents per liter (quart) of formula. Analysis of this product by the FDA revealed 0.091 grams of chloride per quart of formula, or approximately 2.5 milliequivalents per liter.[72] This is approximately 50 percent of the chloride amount indicated by the label.

The subcommittee concludes that Neo-Mull-Soy was mislabeled as to its chloride content in apparent violation of the Food, Drug and Cosmetic Act.

2. *Advertising.*—During its investigation the Subcommittee found that Syntex provided inaccurate information to the medical community about the chloride content of Cho-Free and Neo-Mull-Soy. The 1979 Physicians Desk Reference states on page 1711, under the heading "Cho-Free," that the product contains 0.32 grams of chloride. From the foregoing section, it is clear that chloride concentrations in Cho-Free during the period this PDR was current, were far less.

Moreover, under the Cho-Free reference, the PDR states, "Same formulation as Neo-Mull-Soy except for the absence of added carbohydrates." Given that a content of chloride is stated for Cho-Free and that no mention of either chloride or salt content is made under the listing for Neo-Mull-Soy, practioners could be misled into assuming that Neo-Mull-Soy contained the identical and nutritionally adequate chloride contents represented in Cho-Free. Dr. Roy, in fact, testified that "I went to the product information that I had access to and looked up what the formula was suppose to contain." . . ."It appeared adequate from what the product information said it should contain." [73] Further, in a manuscript accepted for publication in Pediatrics and made available to the subcommittee, Drs. Harvey Grossman and his associates state, in citing the 1979 PDR and discussing the chloride content of Neo-Mull-Soy, "In addition the concentrations of chloride in these batches of formula were considerably lower than the level declared by the manufacturer." [74] Clearly, if Syntex had accurately represented the low chloride content in these products, the ill-effects suffered by at least some of the affected infants would undoubtedly have been prevented.

The subcommittee finds that the 1979 PDR was inaccurate and misleading in the nutritional information that is provided on Cho-Free and Neo-Mull-Soy, in apparent violation of the Food, Drug and Cosmetic Act.

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[70] *EIR–Elgin, supra* note 15, at 14.
[71] *Id.*
[72] FDA Chicago District Office analysis of Ready To Use Neo-Mull-Soy samples obtained Aug. 23, 1979 reported by M. P. Bueno, Dec. 19, 1979.
[73] *Hearings, supra* note 5, at p. 6.
[74] Grossman, H. et al "The Dietary Chloride Deficiency Syndrome," publication forthcoming in Pediatrics.

C. Prohibited Acts (sec. 301)

By virtue of the fact Syntex marketed products that appeared to be in violation of sections 402 and 403,[75] the Subcommittee believes that Syntex also may have violated section 301(a) of the act:

> The introduction or delivery for introduction into interstate commerce of any food, drug, device or cosmetic that is adulterated or misbranded.[76]

In view of the apparent violations of the Food, Drug, and Cosmetic Act, and because the Department of Justice bears responsibility for determining whether prosecution may be warranted, and for prosecuting violations of the act where circumstances warrant, the matter will be referred to the Department for prosecutive opinion.

VII. INFANT FORMULA: CONSIDERATIONS FOR THE FUTURE

A. A unique food requires special consideration

The consequences of a nutritionally inadequate diet on developing infants became readily apparent during the course of the investigation. Infants on chloride-deficient formulas had a poor appetite and were failing to gain weight; moreover, they exhibited failure to thrive and suffered constipation.[77]

While chloride deficiency generally develops slowly, it is known to cause metabolic alkalosis. The onset of symptoms, which include vomiting, diarrhea, and poor growth, may be hastened in infants who receive chloride deficient formulas without other food. All of the infants known to have developed alkalosis while receiving Neo-Mull-Soy were two to nine months old and had no other source of dietary salt.[78]

The effects of using Neo-Mull-Soy for an extended period of time were described at the hearing by Mr. Marvin David Hill, father of Douglas Hill, a victim of chloride deficiency. Douglas was fed Neo-Mull-Soy as his sole food until four months of age.[79] Mr. Hill testified: "We thought we had a normal healthy baby." ". . . four doctors came into our room and they told us they would put the infant on a heart and respiratory monitor and give him an IV (intravenous feeding). The potassium level was so low they were afraid it might cause an irregular heart beat." [80] Mr. Hill further testified that one physician indicated that the blood that was in this child's veins was not of a quality to sustain life.[81] The long term consequences of chloride deficiency are less clear than the acute illness, leaving a nagging uncertainty about the future. Dr. Jose Cordero, a pediatrician, and the principal investigator for the Center for Disease Control representing the Birth Defects Branch, Bureau of Epidemiology testified that: the CDC was developing a registry of affected infants in order to gather data that would help determine possible long term effects of alkalosis due to low chloride levels in baby formula. It is possible that there are other more subtle illnesses and/or symptoms.[82]

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[75] 21 U.S.C. 342, 343.
[76] 21 U.S.C. 331(a).
[77] *Hearings*, *supra* note 5, at p. 9.
[78] *Id.* at pp. 9–10.
[79] *Id.* at pp. 24–25.
[80] *Id.* at p. 15.
[81] *Id.*
[82] *Id.* at p. 10.

With this kind of insideous potential for serious harm, steps must be taken to insure that the compositions of infant formula are nutritionally adequate. Clearly, the dietary requirements of infant formula are unique and call for special consideration.

This need was recognized by the AAP's Committee on Nutrition in 1974, when it deliberated over specific minimum nutrient levels for infant formulas. The committee revised its basic minimum standards and recommended that a product contain the requisite nutrients at the proposed levels before permitting the label "infant formula". The committee explained the basis for its decision as follows:

> Infants grow most rapidly during the first 4 to 6 months of life. Nutrient requirements are most critical in this period, during which nutritional deficiencies can have lasting effects on growth and development."
>
> . . . there is a risk of fostering other forms of malnutrition if the new products do not provide all nutrients needed by the infant." [83]

The subcommittee is persuaded by the AAP's reasoning and agrees with its recommendation. The subcommittee therefore urges Congress to enact legislation creating a unique category of "infant formula" food, that is, food which is intended for use by normal infants as a sole source food and which meets certain minimum nutritional requirements.

B. Testing: An indispensable need

Current FDA regulations do not require infant formulas to be tested for nutritional adequacy by either the manufacturer or the FDA before marketing, at reasonable periods during marketing, or after reformulations. In the case involving Cho-Free and Neo-Mull-Soy, the failure to conduct product testing, after changes in the manufacturing procedure, permitted deficient levels of chloride in the formulas to go undetected until long after infants were stricken.

After Syntex eliminated salt from formulas for Neo-Mull-Soy and Cho-Free in late 1977, the company did not conduct any chloride assays on the products during the year and a half that followed.[84] Mr. Freiman, President of Syntex, testified that the chloride assays had been discontinued by Syntex as a result of the decision of a company nutritionist in its Elgin, Ill., plant, who considered the assay an elective procedure. According to Mr. Freiman, responsible officials within Syntex were not informed of this change in analytical procedure.[85]

Mr. Freiman admitted during a colloquy with Congressman Gore that the failure to test after reformulation of the product was a mistake:

> Mr. GORE. You reformulated your product after the testing for chloride was stopped, is that correct?
>
> Mr. FREIMAN. That is correct.
>
> Mr. GORE. And you didn't test for chloride after the reformulation. Is that correct?

[83] "AAP Standards," *supra* note 3.
[84] EIR-Elgin, *supra* at 14.
[85] Hearings, *supra* note 5 at 80.

Mr. FREIMAN. That is correct.
Mr. GORE. Another mistake, wasn't it?
Mr. FREIMAN. Yes.[86]

What is particularly disturbing with respect to Syntex's performance, however, is that the company apparently did not learn from its mistakes. After the near-tragic situation involving Cho-Free and Neo-Mull-Soy was discovered and the recall completed, Syntex planned to introduce a new reformulated product without prior testing of nutritional content. When asked during the hearing whether the new product, scheduled for sale to the public in November 1979, had been tested for chloride Mr. Freiman admitted that testing had not been conducted.[87] [88]

When Mr. Mottl questioned Mr. Freiman specifically on the issue of testing, Mr. Freiman's response did not comport with his company's actions.

> Mr. MOTTL. Wouldn't you agree after this incident looking back a little bit that either your company or the FDA or both should have some pretesting of the formula since our youngsters, our babies of such tender years, have no alternative in many instances for their health and welfare.
>
> Mr. FREIMAN. "Let me say that the concern you are expressing is a concern we have as well.[89]

Clearly, under current law, the potential exists for repetition of this unfortunate episode. The subcommittee therefore recommends that Congress enact legislation requiring, at a minimum, that "infant formulas" be tested for nutritional components before marketing and after any reformulation or other change in the manufacturing process. Consideration should also be given to requiring similar testing at periodic intervals during marketing.

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[86] *Id.* at p. 90.
[87] *Id.*
[88] Subsequently, the new Syntex products were cleared by FDA for introduction into commerce after the composition of the reformulated products were found to be adequate.
[89] *Id.* at p. 97.

DISSENTING VIEWS OF THE HONORABLE NORMAN F. LENT

RANKING MINORITY MEMBER OF THE
SUBCOMMITTEE ON OVERSIGHT AND INVESTIGATIONS

CONCURRING IN THESE VIEWS ARE HONORABLES:

JAMES T. BROYHILL
TOM CORCORAN
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DISSENTING VIEWS OF THE HONORABLE NORMAN F. LENT

I must strenuously dissent from the issuance of this report insofar as it refers this investigation to the Department of Justice for possible criminal prosecution (See Recommendation III C). I had been prepared to vote to approve this report,* even though the report overstates somewhat the actual events, because of the extreme importance of assuring that infant formula is both safe and effective. I still feel this to be extremely important.

However, a recommendation of criminal prosecution in this situation represents a quantum leap beyond the facts herein, and beyond what is necessary to achieve the goal of safe and effective formulas. Moreover, such a referral usurps the statutory duty and responsibility of the FDA, runs roughshod over the due process rights of the individuals involved, and is counter-productive to the goal of assuring parents, whose allergy-suffering infants must depend on these particular products, that the products are indeed safe and effective.

Consequently, I will explore my reasons for strenuously dissenting from issuing this report with the referral language intact. Thus, these views will look at Syntex as a company, its behavior in this episode, and then examine the Subcommittee's decision to refer the episode to Justice.

I.

Syntex is a diversified company which specializes in human pharmaceuticals. Its products, in addition to infant formulas, include anti-inflammatory drugs to combat arthritis, topical gels for the treatment of skin disorders, oral contraceptives, dental supplies, and diagnostical aids both for the detection of drug abuse and for screening for proper drug dosages. It has never had problems of this nature before this episode. The question is whether Syntex acted responsibly after it learned of the problems with the formula?

What was wrong with the formula? Since the products have been on the market for over ten years, the company had no reason to believe the formula was deficient. It had purchased the baby formula operation from the Borden Company and had been producing formula at its Elgin, Illinois, plant. However, several individual occurrences coalesced to result in the chloride content of these products becoming too low.

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* In the Subcommittee's deliberations, I made a motion to delete Recommendation III C, and issue the report except for the referral to Justice. My motion was defeated 6 to 4.

First, the company had responded to prevailing scientific and medical opinion a few years earlier, to reduce salt levels in formula. The reason was that too much salt in infants' diets caused a craving for it later in life, which could result in high blood pressure and hypertension. Second, the water used in making the formula was changed. The new supply had less chlorination and no fluoridation -- further reducing chloride levels. Third, the company changed suppliers of soy protein. The new supply had little or no salt.

The convergence of these events resulted in products with too little salt for those infants on them as a sole source. In fact, throughout most of its existence Neo-Mull-Soy had been used primarily as a supplement. None of these events, of course, absolves the company of liability for too little salt -- the company officials admitted at the hearing that it was a mistake, albeit an honest one.

I would like to dwell for a moment on the nature of these two formulas. They are very specialized and represent for some infants the only safe food in the early months of life, due to allergies to milk (mother's or cow's), wheat, oats, corn fractions, etc. Syntex offered at the hearing, and has subsequently supplied to me, many letters from doctors and concerned parents all over the country, pleading for these products to be returned to the market. The involved infants, without these formulas, were suffering from all manner of food-related allergies causing vomiting, colic, irritability, nasal and ear problems -- some actually were admitted to hospitals for stays up to five days because of intolerance to other foods.

I think that it is important to keep this episode in context. By this, I do not mean that Syntex should not be blamed for allowing the salt content to reach dangerously low levels. However, on a nationwide basis, the number of infants affected was very small. The fact that Syntex recalled and destroyed over 8 million cans of product gives some idea of how many infants were on this formula <u>without</u> ill effects.

How important does the FDA believe this type of product to be? Dr. Jere Goyan, Commissioner of FDA, has stated that infant formulas of this type are "uniquely important to the health of this Nation." It is interesting to note that the FDA tested the reformulated products and cleared them for re-entry into the market by telegram to Syntex on December 17, 1979, a mere 6 weeks after the hearings. I mention this by way of contrast to the majority's view that Syntex was rushing to dump this product back on the market right after the recall, because of ill motives. The truth is just the opposite. The company was responding to a dire need for its products all across the country.

Also, on that point, I would like to clear up a misconception from the hearing. The company was asked at the hearing whether it had pre-tested the formulas prior to attempted re-marketing in the fall of 1979 after the recall. They Syntex witness answered in the negative; but the reason was that he misunderstood the question under the rigors of cross-examination. By pre-market testing the witness thought was meant the use of live infants, which were not

used. However, pre-market tests were done on the composition of the formula by assay prior to the re-marketing.

Much has been made, and properly so, about the long-term effects of chloride deficiency in the involved infants. The fact of the matter is that no one knows what effects there will be, if any. The FDA has much evidence that the infants, once given sufficient chloride, returned to normal growth, and thrived.

We all hope very deeply that this is the case, and that there will not be any long-term effects. Syntex, on its own, and with the National Institute of Health, is formulating specific plans to follow up the progress of all involved infants. Thus, I do not believe that it serves the best interests of any of the parties involved for the Subcommittee to trumpet the most frightful possibilities, none of which can now be evidenced as likely.

In summary, insufficient chloride levels caused grave reactions in some children being fed Neo-Mull-Soy or Cho-Free as their sole source of nutrition for extended periods. Syntex erred and properly is being held accountable.

However, the record of Syntex' actions upon discovering the low chloride levels describes a company moving quickly and responsibly to recall a defective product, to correct its mistake and to work to insure that another similar incident cannot occur. Most importantly, it shows a company deeply concerned about the affected infants and committed to monitoring their development.

In testimony before this Subcommittee, Dr. Roger Erickson of the Center for Disease Control in Atlanta, when I asked about Syntex' cooperation with himself and CDC's Dr. Jose Cordero, stated:

> From all I know about my contacts with them (i.e. Syntex) and those of Dr. Cordero's they have been extremely cooperative. It seems to us that they have moved rather expeditiously in calling a meeting of experts and in deciding to recall their product. (Infant Formula Hearings; 96 IFC 79 18,19)

I have had developed a chronology of Syntex' actions relating to the Neo-Mull-Soy and Cho-Free recalls which details the company's actions. The facts are quite different from the impressions presented by the majority.

Chronology of Syntex' Actions

Relating to the Neo-Mull-Soy and Cho-Free Recalls

July 1979 : Syntex begins to receive reports from doctors of several cases of metabolic alkalosis occurring in infants who were using Neo-Mull-Soy.

July 28, 1979 : Three days after receiving several reports Syntex sends Western Union Mailgrams to all pediatricians and other physicians who specialize in treating infants in the United States - about 24,000 doctors. The Mailgrams suggest the doctors maintain "suitable vigilence"; that "Syntex and its expert consultants are currently engaged in a careful review of the reported cases"; that "we are also evaluating the possibility that chloride levels in Syntex' soy formulas may not be sufficient for the protection of certain individual patients"; and that further information would follow.

FDA was read the Mailgram over the telphone as soon as it was composed; Syntex keeps FDA informed daily of all events relating to the recall.

July 28 - 31, 1979 : Syntex invites a group of expert doctors to meet with Syntex experts, at company expense, as soon as possible.

The group includes nutrition specialists, a physician from the Center For Disease Control and some of the doctors who had reported cases to the company, including Dr. Shane Roy of Tennessee.

August 1, 1979 : The group of expert doctors meets with company experts and provides advice.

August 1, 1979 : Syntex decides to voluntarily recall Neo-Mull-Soy and Cho-Free immediately.

August 1, 1979 : Syntex immediately telephones the FDA recall coordinator to ask that he clear the company's recall documents as soon as possible.

August 1 - 2, 1979 : Syntex works through the night and morning of the next day to prepare the procedures and documents needed to implement a complete recall.

August 2, 1979 : Syntex recall documents are approved by FDA; recall goes into high gear.

August 2, 1979 : Syntex sends Mailgrams to the approximately 24,000 pediatricians and other specialists to whom Syntex' first Mailgram had gone. The

Mailgram describes the symptoms of children who had encountered problems, informs doctors of the recommendation of the panel of experts concerning appropriate corrective medical measures, and asks the doctors to quarantine any cans in their offices until Syntex picks them up.

August 2, 1979 : Syntex sent a first class letter, marked on the envelope with the words "URGENT PRODUCT RECALL" to over 100,000 physicians (every doctor that could reasonably be expected to encounter the situation) and to pediatric nurses. The letters repeat information in the Mailgram sent to doctors, describing the symptoms of children, the recommendation of the panel of experts concerning corrective medical measures, and asking that any cans be quarantined until Syntex picks them up.

August 2, 1979 : Syntex releases nationally a press statement designed to alert mothers and other consumers about the recall. It is covered by television, radio and newspapers throughout the United States.

August 2, 1979 : Syntex notifies everyone to whom it sells Neo-Mull-Soy and Cho-Free by sending first class letters, in envelopes marked "URGENT PRODUCT RECALL" in red, to all wholesalers, hospitals, food markets and drug stores who are customers. A similar letter was sent to food brokers.

August 1979 : Syntex contacts virtually all of its customers in order to insure that products were removed from store shelves.

August 1979 : Syntex orders all its 400 salesmen to go beyond their normal rounds into pharmacies, food stores, and other places where the products might be marketed to spread the word of the recall. Over 26,000 visits are made by the company's sales force in order to help remove product from the market.

September 1979 : Syntex consults its own experts and independent pediatric-nutrition specialists (including the present and former chairman of the Committee on Nutrition of the American Academy of Pediatrics) and reformulates Neo-Mull-Soy and Cho-Free to assure appropriate levels of all ingredients, including chloride.

September 1979 : Syntex institutes extraordinary checking and inventory procedures for lots of Neo-Mull-Soy and Cho-Free.

September - October 1979 : Syntex laboratory tests Neo-Mull-Soy and Cho-Free to insure appropriate levels of all ingredients including chloride.

September 7, 1979	:	Syntex again sends first class letters in envelopes marked "URGENT: PRODUCT RECALL" to all its customers in order to further impress upon them the need to contact their customers to insure the few remaining isolated cans of product are off the shelves.
August 1979 -	:	Syntex, independently and with NIH, is formulating specific plans to follow-up on the progress of all children reported to it to have had adverse reactions to Neo-Mull-Soy and Cho-Free.
September 1979 Present	:	Syntex is reviewing, revising and rewriting its normal quality control and assurance procedures to insure there is no possibility of any recurrence of this or any similar situation.

II.

Proper procedures may not always insure fairness, but improper ones almost always guarantee abuses. The majority's decision to refer the Neo-Mull-Soy and Cho-Free incidents to the Department of Justice for prosecution is a travesty of due process.

From a simple oversight hearing, the majority has leapfrogged into a usurpation of the powers of the FDA; and, in the process has trampled upon the due process rights of the individuals who stand to be prosecuted for what can, at the most, be termed technical violations of the pertinent statutes. It is one thing to conduct oversight -- it is quite another to preempt the normal functions of the FDA, including the procedural safeguards built into the administrative process.

Of course, the argument can be made -- as it was in the Subcommittee's deliberations on my motion to remove the referral from this report -- that this is merely a "routine" referral, and that it is highly unlikely that Justice will return an indictment, and so on. This is cold comfort for the employees of Syntex.

Worse, it is a specious argument, because the Syntex Company stands to be severely damaged, and have its reputation ruined, by the avalanche of adverse publicity, which is sure to follow such a referral. In fact, the Company has been vilified by the media on numerous occasions already. The worst thing is that the parents of infants absolutely dependent on these specialized products will have trauma anew when this report is released.

Thus, I believe it important to their peace of mind and to fair play, that the current system of prosecution of criminal violations be set forth. All must be assured that there is in place a mechanism -- an effective mechanism -- for the prosecution of real criminal violations. At the same time, this mechanism must be shown to afford procedural and substantive due process to those accused.

Beginning some 75 years ago, Congress has developed this mechanism to regulate the food and drug industry, which, of course, includes infant formula manufacturers. Procedures have evolved to insure the fair hearing to which every individual is entitled.

There is a clear and logical process involving many critical decision points within the Food and Drug Administration, which must take place before as serious a step as referring a matter to the Department of Justice is taken. These procedures relate to Section 305 of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. Section 335, which states:

> HEARING BEFORE REPORT OF CRIMINAL VIOLATION
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> Sec. 305 [335]. Before any violation of this Act is reported by the Secretary to any United States attorney for institution of a criminal proceeding, the person against whom such proceeding is contemplated shall be given appropriate

notice and an opportunity to present his views, either orally or in writing, with regard to such contemplated proceeding.

Let me trace from start to finish how the process works in practice. An incident occurs. The local District Office of the Food and Drug Administration initiates a preliminary investigation to look into it. After gathering information, the District Office determines if, in its opinion, a violation of the Food, Drug and Cosmetic Act has occurred. Decision point one.

If it believes such is the case, the FDA District Office then takes steps to decide whether such a violation warrants referral to the Department of Justice for criminal prosecution. Often, further investigation is undertaken, facts are reviewed, considerations balanced and finally an opinion formulated. Decision point two.

If the District Office decides no referral to Justice is proper, the matter stops here. If it thinks otherwise, it sets forth in writing the charges facing the company and the individual and provides them with the opportunity to appear in person before the District Office to present reasons why the matter should not be referred for criminal prosecution. The potential defendant can make his case to the agency, explaining why events occurred, the surrounding circumstances and the like. He is entitled to a transcript of hearing. These procedures are detailed in 21 C.F.R., Chapter 1, (Food and Drug Administration) Subpart E - Criminal Violations, Section 7.84, Opportunity for Presentation of Views before Report of Criminal Violation.

After this evidence is received, the District Office makes a determination whether to recommend to FDA Headquarters in Washington, D.C. that the matter be referred to the Department of Justice for criminal prosecution. Decision point three.

The District Office can simply recommend no. Or it can recommend yes. If the latter is the case, FDA Headquarters takes the evidence gathered by its District Office, the reports of its investigators and the hearings, reviews them again and formulates an independent opinion to determine if referral to the Justice Department is warranted. Decision point four.

FDA Headquarters can recommend no further action. If so, the matter ends. Or it can forward the case to the Department of Justice for prosecution. If it does the latter, Justice can either initiate procedures to commence or it can veto FDA's recommendation. Decision point five.

The proper purpose of this Subcommittee should be to conduct oversight of agencies under our jurisdiction to determine whether their procedures afford due process. This does not include the abrogation or usurpation of their functions. The FDA procedures detailed above comport with due process.

The dangers inherent in the Subcommittee's actions, in my opinion, reach far beyond the dimensions of the Syntex case. Ours is a Subcommittee historically dedicated to the protection of due

process rights. Indeed, one of the Subcommittee's principal investigations during 1978 -- into charges that the NCAA flouted the due process rights of institutions and student athletes -- reaffirmed that commitment. In fact, the Subcommittee, in its findings concerning the investigative portion of the NCAA's activities concluded:

> The Subcommittee finds that NCAA member institutions under investigation have been given inadequate notice of the procedures allowed or encouraged by the NCAA under which the institution is required to respond to allegations and prepare its defense.
>
> The Subcommittee finds that there is a pervasive appearance throughout the investigative process that member institutions subject to letters of Official Inquiry are presumed guilty until proved innocent, which the Subcommittee finds fatally offensive to its sense of fair play. Such presumption extends to student athletes and other individuals subject to allegations. (NCAA Investigation: 95 IFC 69, p. 25)

In my opinion, the majority report, insofar as it recommends referral of this investigation to the Justice Department for prosecution, unnecessarily goes far beyond the legitimate interests of this Subcommittee, and injects it into an area properly within the jurisdiction of the FDA. Even assuming that the facts brought out by the Subcommittee warranted prosecution -- which I do not believe can be so interpreted by a reasonable person -- it is far preferable to remand the case back to the FDA for further examination, rather than risk trampling the due process rights of individuals by direct referral. Worse yet is the distinct possibility that the Subcommittee's actions will result in a trial by media, in which a company -- which I believe to be a responsible one -- is found guilty, and is irreparably harmed.

Only when clear and convincing evidence of substantial violation of law is uncovered by this Subcommittee should direct referral be made. In the Syntex case, the evidence falls far short of this standard, and is, in fact, extremely weak.

In closing, I would only point to one sentence in the report which, to my mind, is indicative of the lack of a basis for this referral. In Section VI A of the report, the Subcommittee goes a somewhat tortuous path in an effort to make a showing that the products were "adulterated" in the legal sense of the word. However, in order to make this showing, it must be shown that chloride is a valuable constituent of the food. The sentence reads:

> Clouding the issue of chloride's value is the fact that FDA regulations in effect at the time of this incident did not list chloride as one of the important ingredients in infant formula.

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